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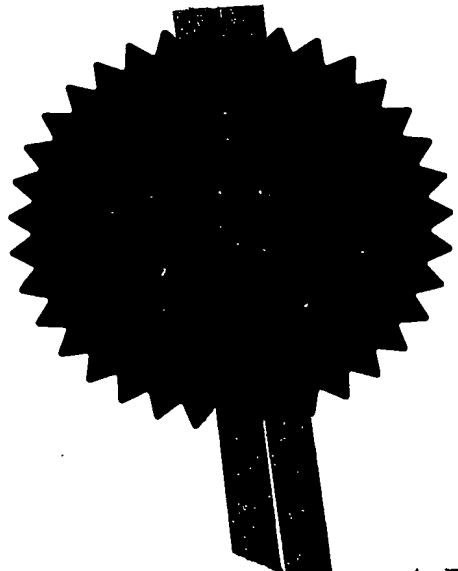
I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

I also certify that the application is now proceeding in the name as identified herein.

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Signed *Andrew Gersey*  
Dated 30 April 2004

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GB.0307082.8

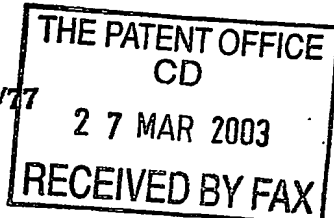
By virtue of a direction given under Section 30 of the Patents Act 1977, the application is proceeding in the name of:

MPATHY MEDICAL DEVICES LIMITED,  
6.05 Kelvin Campus,  
West of Scotland Science Park,  
GLASGOW,  
G20 0SP,  
United Kingdom

Incorporated in the United Kingdom,

[ADP No. 08730905001]

Patents Form 1/77

Patents Act 1977  
(Rule 16)27MAR03 E795753-1 D02884  
P01/7700 0.00-0307082.8**Request for grant of a patent***(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)*

The Patent Office

Cardiff Road  
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1. Your reference	P29925-/CMU/RTH/RMC		
2. Patent application number <i>(The Patent Office will fill in this part)</i>	0307082.8		27 MAR 2003
3. Full name, address and postcode of the or of each applicant <i>(underline all surnames)</i>	Gyne Ideas Limited 1 Bell Leys Wingrave Buckinghamshire HP22 4QD United Kingdom		
Patents ADP number <i>(if you know it)</i>	SECTION 8(1)(977 ACT) APPLICATION FILED 4/3/04 824642001		
If the applicant is a corporate body, give the country/state of its incorporation	United Kingdom		
4. Title of the invention	"Drug Delivery Device and Method"		
5. Name of your agent <i>(if you have one)</i>	Murgitroyd & Company		
"Address for service" in the United Kingdom to which all correspondence should be sent <i>(including the postcode)</i>	Scotland House 165-169 Scotland Street Glasgow G5 8PL		
Patents ADP number <i>(if you know it)</i>	1198013 <sup>5</sup>		
6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and <i>(if you know it)</i> the or each application number	Country	Priority application number <i>(if you know it)</i>	Date of filing <i>(day / month / year)</i>
7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application	Date of filing <i>(day / month / year)</i>	
8. Is a statement of inventorship and of right to grant of a patent required in support of this request? <i>(Answer 'Yes' if:</i> <i>a) any applicant named in part 3 is not an inventor, or</i> <i>b) there is an inventor who is not named as an applicant, or</i> <i>c) any named applicant is a corporate body.</i> <i>See note (d))</i>	Yes		

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9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description	26
Claim(s)	-
Abstract	-
Drawing(s)	5

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (*Patents Form 7/77*)Request for preliminary examination and search (*Patents Form 9/77*)Request for substantive examination (*Patents Form 10/77*)Any other documents  
(please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

*Murgitroyd & Company*

Date

27 March 2003

Murgitroyd &amp; Company

12. Name and daytime telephone number of person to contact in the United Kingdom

ROISIN MCNALLY

0141 307 8400

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**Patents Form 1/77**

1 "Drug Delivery Device and Method"

2

3 This invention relates to a drug delivery device and  
4 a method of delivering a drug.

5

6 There is a huge number of drugs which may be  
7 administered to the human and animal body for the  
8 prevention or treatment of disease. Different types  
9 of drugs call for different ways of administering  
10 the drug to the human or animal body.

11

12 Perhaps the most common method of delivering a drug  
13 is by ingestion. In other words, drugs are provided  
14 in pill, capsule, powder or liquid form for oral  
15 administration to a human or animal. The drug is  
16 then absorbed by the digestive system and will  
17 usually enter the blood stream via the liver to take  
18 effect. However, far from all drugs are suitable  
19 for such administration. For example, many drugs  
20 would be broken down by the digestion process and  
21 destroyed before they can enter the blood stream.  
22 This problem is caused by what is commonly referred  
23 to as the "first pass liver metabolism" of the human

1 or animal body, i.e. the process by which all  
2 substances absorbed by the digestive system must  
3 pass through the liver into the blood stream.

4  
5 Another very common way in which drugs are  
6 administered, which avoids the problems of the first  
7 past liver metabolism, is by injection. Drugs  
8 desired to take an instant effect in the blood  
9 stream of a human or animal body may be injected  
10 into a vein, i.e. intravenously. Alternatively,  
11 drugs may be injected into muscle tissue from which  
12 the drug is absorbed more slowly into the blood  
13 stream. Drugs for injection into muscle tissue may,  
14 for example, be provided in an oily base which helps  
15 to regulate the rate of absorption. However,  
16 injections can be painful and difficult,  
17 particularly injections into muscle tissue, and can  
18 lead to tissue damage where frequent injections are  
19 required on a long term basis, e.g. of insulin for  
20 diabetics. Other types of drug delivery include  
21 nasal sprays for administration of drugs to the  
22 nasal tissues and lungs; patches, such as the  
23 Nicorette® patch, for the application of drugs, e.g.  
24 Nicotine, through the skin; and lotions or ointments  
25 for topical application, i.e. directly to an  
26 affected part of the body.

27  
28 All of the above drug delivery methods are useful  
29 for particular types of drugs and medicines, but are  
30 unable to provide therapeutic levels of drugs over a  
31 long term, e.g. weeks and months rather than days,

1 without repeated application by the patient or a  
2 carer.

3  
4 For passive application of drugs on a long term  
5 basis, various implants have been developed. One  
6 such type of implant may be inserted under the skin  
7 and have a mechanism for slowly releasing a drug  
8 into the blood stream of the human or animal in  
9 which it is implanted. For example, Norplant® or  
10 Implanon® comprise an implant having small capsules  
11 or rods which slowly release levonorgestrel or  
12 etonorgestrel into the blood stream to provide a  
13 contraceptive effect for women. Norplant® can be  
14 effective for up to five years. However, the  
15 insertion of such an implant is painful and requires  
16 local anaesthesia on both insertion and removal.  
17 Furthermore, implantation can cause significant  
18 bruising and discomfort. In addition, as such  
19 implants are placed under the skin in for example  
20 the arm, they can be visible and cause  
21 discolouration of the skin. As the arm contains  
22 many different types of tissue and planes of tissue,  
23 movement of the implant along or through these  
24 tissue planes can occur. This can mean the implant  
25 moves to locations other than where it was placed  
26 during insertion which can lead to complications for  
27 the patient, in particular during removal of the  
28 implant. Difficulties with the Norplant® implant  
29 has led to it being withdrawn from clinical use.

30  
31 Another type of implant is a contraceptive coil or  
32 intrauterine device, IUD or IUCD which is placed in

1 the uterus to provide a contraceptive effect. A  
2 coil may be impregnated with hormones such as  
3 levonorgestrel to reduce the thickening of the  
4 endometrium of the uterus during the menstrual  
5 cycle. Likewise vaginal rings, comprising soft  
6 plastic rings of around 4cm to 5cm in diameter  
7 impregnated with a desired drug, are sometimes used  
8 for hormone replacement therapy. Vaginal rings are  
9 placed in the vagina around the cervix where they  
10 can slowly release a drug into the bloodstream  
11 through the soft tissue of the cervix. However,  
12 such vaginal rings are uncomfortable during sex and  
13 both vaginal rings and coils can lead to vaginal  
14 discharges and general discomfort to the wearer.  
15 Coils in particular can cause severe discomfort,  
16 such as stomach cramps, due to the direct  
17 application of levonorgestrel to the uterus.

18  
19 According to the present invention there is provided  
20 a drug delivery device comprising an implant for  
21 insertion into the myometrium (the smooth muscle of  
22 the uterus).

23  
24 In one embodiment the implant comprises a point to  
25 facilitate insertion into the myometrium and a body  
26 in which a drug can be held prior to delivery.

27  
28 The implant may further comprise insertion and / or  
29 retrieval means to allow manipulation. This is  
30 advantageous over implants previously known in the  
31 art as the myometrium has few somatic (pain) nerves.  
32 Further there is little tissue or muscle movement in



5

1 the myometrium compared with for example the tissues  
2 of the arm or the leg. In addition, the myometrium  
3 does not comprises as many layers or planes of  
4 tissue as in the arm or leg, minimising the  
5 likelihood of movement of the implant following  
6 insertion to a different location.

7  
8 There is also provided a method of delivering a drug  
9 comprising inserting at least one drug delivery  
10 device into the myometrium.

11  
12 The myometrium is the smooth muscle of the body of  
13 the uterus and the cervix.

14  
15 Preferably the drug delivery device is an implant  
16 which can be inserted into the myometrium, for  
17 retention therein.

18  
19 Preferably the drug delivery device is an implant  
20 which can be inserted into the myometrium, for  
21 retention therein for a defined period of time.

22  
23 The retention of the implant in the myometrium for a  
24 defined period of time allows the delivery of a drug  
25 to the surrounding tissues and bloodstream over a  
26 period of time.

27  
28 Preferably access to the myometrium is via the  
29 vagina through the cervix. This has the advantage  
30 that the implant can be suitably located using a  
31 speculum in an outpatient setting. The insertion of  
32 the implant in the myometrium would be similar in

1 both the time taken and the discomfort to the  
2 patient as the taking of a smear.

3

4 Preferably the implant is located in the myometrium  
5 of the cervix. Vaginal access allows the implant to  
6 be located in the myometrium of the cervix and the  
7 location of the implant can be checked by speculum  
8 examination following implantation.

9

10 Alternatively access to the myometrium may be  
11 available during open or laproscopic surgery. This  
12 has the advantage of allowing the implant to be  
13 placed at any suitable location in the myometrium,  
14 usually of the body of the uterus. The implant may  
15 thus be placed in the myometrium of the body of the  
16 uterus, or other positions which would not be  
17 accessible by access via the vagina.

18

19 According to another aspect of the present invention  
20 there is provided a drug delivery device comprising  
21 an implant for insertion into the prostate gland.

22

23 There is also provided a method of delivering a drug  
24 comprising inserting at least one drug delivery  
25 device into the prostate gland.

26

27 Preferably the drug delivery device is an implant  
28 which can be inserted into the prostate for  
29 retention therein.

30

31 This has the advantage that drugs can be delivered  
32 to the tissue of the prostate, surrounding the

1 prostate, and the bloodstream. Further, delivery of  
2 drugs directly to the prostate means the drugs are  
3 not subjected to liver metabolism as would be the  
4 case for drugs provided orally.

5  
6 Preferably the drug delivery device is an implant  
7 which can be inserted into the prostate for  
8 retention therein for a defined period of time.

9  
10 This has the advantage that drugs can be supplied to  
11 the tissue of the prostate, the tissue surrounding  
12 the prostate, and the bloodstream over a period of  
13 time.

14  
15 Preferably the defined period of time is between 1  
16 month and 5 years from insertion of the implant.

17  
18 In other words, in one embodiment a drug delivery  
19 device is implanted in the myometrium where it  
20 releases a drug for absorption through the smooth  
21 muscle and soft tissue into the blood stream.

22  
23 Alternatively, a drug delivery device is implanted  
24 in the prostate where it releases a drug for  
25 absorption into the blood stream.

26  
27 The drug delivery device of the present invention  
28 differs from the coil or a vaginal ring as disclosed  
29 in the prior art, in that the drug delivery device  
30 is actively inserted into the tissue of the  
31 myometrium. The coil is located in the cavity of  
32 the uterus (endometrium) and vaginal rings are

8

1 placed at the top of the vagina around the cervix.  
2 These devices of the prior art therefore differ from  
3 the delivery device of the present invention which  
4 is actively inserted into the smooth muscle of the  
5 cervix or of the uterine body (myometrium).

6

7 Preferably the implant comprises an insertion point  
8 and a body including a drug carrying medium which  
9 includes the drug to be administered.

10

11 The drug is therefore administered by release from  
12 the medium, e.g. by the medium dissolving.

13

14 Preferably the body is retrievable at the end of the  
15 drug application, e.g. after a few weeks, months or  
16 years. This has the advantage that the drug  
17 delivery means are not left in the body forever and  
18 further provides a means for controlling the amount  
19 of drug given and the time over which the drug is  
20 provided. It can also be removed if the patient  
21 requests for any reason or if problems are  
22 encountered.

23

24 The body may be any material which is capable of  
25 providing a semi-sharp point.

26

27 Preferably at least the insertion point is metallic.

28

29 The myometrium surrounding the uterus and vaginal  
30 cavity has very few or no somatic sensory (pain)  
31 nerves and insertion and retention of the implant in

1 this smooth muscle and tissue is therefore  
2 substantially painless for the patient or wearer.

3  
4 This has significant advantages over conventional  
5 implants such as Norplant® which are inserted under  
6 the skin. Unlike these conventional implants which  
7 are inserted into the skin, which has sensory nerves  
8 and into which insertion is painful, the implant  
9 described by the present invention is inserted into  
10 tissues which have minimal numbers of sensory  
11 nerves. In addition the minimal number of sensory  
12 nerves in the myometrium means that withdrawal of  
13 the implant is substantially painless and the  
14 presence of the implant during use is not painful  
15 and minimal discomfort is experienced by the  
16 patient. In effect the implant is "invisible" to  
17 the patient, but visible to the clinician if  
18 required.

19  
20 The location of the implant within the smooth muscle  
21 of the cervix and uterus provides a novel means of  
22 drug delivery to a specific location in the body.  
23 The location of the implant promotes rapid  
24 absorption of released drug and the released drug  
25 does not require to undergo liver metabolism. In  
26 addition, drug delivery by means located within the  
27 tissue of the myometrium minimises problems of  
28 absorption through mucosal layers overlying tissues,  
29 as experienced in drug delivery means placed around  
30 tissues or in cavities such as vaginal rings and  
31 intrauterine devices.

32

1 Preferably, the drug delivery device of the present  
2 invention is significantly smaller than coils, IUD  
3 or vaginal rings. This is advantageous as there  
4 will be less discomfort to the person in which the  
5 drug delivery device is implanted and less  
6 likelihood of rejection of the implant by the body  
7 or responses such as inflammation.

8  
9 The drug delivery device of the present invention is  
10 inserted in and retained in the smooth muscle of the  
11 myometrium. This differs from the location of  
12 intrauterine devices and vaginal rings which are not  
13 inserted into tissue or smooth muscle, but instead  
14 are placed within the cavity of the uterus or in the  
15 vaginal cavity around and not within the tissue of  
16 the cervix.

17  
18 Preferably the implant does not therefore cause any  
19 discomfort to the wearer during use.

20  
21 Another advantage of the present invention is that  
22 insertion of the implant into the myometrium  
23 provides efficient absorption of the drug. The  
24 vaginal cavity is lined or covered with mucus, i.e.  
25 vaginal mucosa. Drugs released from a vaginal ring  
26 must pass through the vaginal mucosa before being  
27 absorbed into the vaginal wall and passing into the  
28 blood stream. In contrast, as the implant of the  
29 present invention is located in the myometrium,  
30 drugs released from the implant pass directly into  
31 the smooth muscle and blood stream. This is  
32 advantageous as it provides for systemic delivery of

11

1 drugs which unlike drugs provided orally do not  
2 require to undergo liver metabolism on entry into  
3 the body.

4  
5 The myometrium has a high density of blood vessels  
6 and is therefore particularly suited to absorbing  
7 drugs released from the implant. The myometrium is  
8 also in a convenient location, at the top of the  
9 vaginal cavity, for insertion and removal of the  
10 implant. This is advantageous as it allows the  
11 implant to be placed by vaginal access in an  
12 outpatient setting. Further, the location of the  
13 implant can be easily checked by speculum  
14 examination.

15  
16 Preferably the implant is inserted and retained in  
17 the smooth muscle tissue of the cervix.

18  
19 Preferably the implant is inserted into the smooth  
20 muscle of the cervix via the vagina.

21  
22 Alternatively the implant is inserted into the  
23 myometrium through serosa surrounding the  
24 myometrium.

25  
26 In a further alternative the implant is inserted  
27 into the myometrium through the transendometrium.

28  
29 The prostate is a gland in males which surrounds the  
30 top of the bladder.

31

12

1 Preferably insertion of an implant into the prostate  
2 is by a transrectal route.

3

4 Alternatively the implant can be inserted into the  
5 prostate by a trans perineal route.

6

7 Preferably insertion of an implant is performed  
8 using ultrasound.

9

10 As mentioned above, the implant may comprise a body  
11 and drug delivery means. More specifically, the  
12 implant may comprise a metallic, e.g. surgical  
13 steel, body.

14

15 Preferably the body comprises a first end which  
16 includes a semi-sharp point, a middle portion which  
17 provides for drug delivery and retrieval means at  
18 second opposite end of the body. It is advantageous  
19 if the retrieval means allow the location of the  
20 body to be determined by either visual or physical  
21 examination.

22

23 The body can be of any shape which allows  
24 implantation.

25

26 Preferably the body is elongate. This allows the  
27 implant to be easily inserted into the tissue.

28

29 In cross section the body can be of any preferred  
30 shape to influence the drug delivery characteristics  
31 of the implant. For example the body may be cross



13

1 shaped to increase the surface area of the body  
2 exposed to the surrounding tissue.

3

4 Preferably the body has maximal surface area in  
5 relation to its length or volume. This has the  
6 advantage of providing maximal absorption of the  
7 drug into the surrounding tissues and / or smooth  
8 muscle.

9

10 Preferably along the length of the body is at least  
11 one drug delivery means.

12

13 Preferably the drug delivery means comprises a  
14 medium carried by the body, in which medium the drug  
15 to be administered is carried.

16

17 Alternatively, the implant may be a homogeneous  
18 unit. For example the body may be formed from the  
19 medium carrying the drug. The medium carrying the  
20 drug may be absorbable.

21

22 In one embodiment the implant is non-absorbable.

23

24 Alternatively the implant is at least partially  
25 absorbable.

26

27 The medium carrying the drug may be enclosed by the  
28 body.

29

30 Alternatively the medium carrying the drug is not  
31 enclosed by the body.

32

14

1 The implant itself may be the medium in which the  
2 drug to be administered is carried. In this  
3 example, the implant can be soluble. The entire  
4 implant can therefore be absorbed over the period of  
5 time that the drug is administered.

6  
7 The implant may have any structure suitable for  
8 insertion and retention in the smooth muscle of the  
9 myometrium or the tissue of the prostate. For  
10 example the implant may comprise barbed portions or  
11 surface patterns to promote retention of the implant  
12 in the myometrium or prostate. This may be  
13 advantageous if movement of the tissue in which the  
14 implant is inserted is likely to cause the implant  
15 to work loose and move from its intended position.

16  
17 Preferably, the implant is generally needle shaped  
18 or the implant is a needle.

19  
20 Alternatively the implant comprises a pointed metal  
21 spiral attached to means which allows the implant to  
22 be moved into the myometrium or the prostate.

23  
24 The means which allow the implant to be moved into  
25 the myometrium or the prostate may also allow the  
26 removal of the implant from the myometrium or the  
27 prostate.

28  
29 Preferably the implant is corkscrew shaped.

30  
31 Preferably the implant has a point at one (distal)  
32 end for aiding insertion of the implant into the

15

1 myometrium or the prostate. This is advantageous as  
2 it allows the implant to be easily inserted into the  
3 smooth muscle of the myometrium or the tissue of the  
4 prostate. The implant can therefore be pressed into  
5 the myometrium using the pointed distal end.

6  
7 Alternatively, an insertion tool is provided having  
8 a pointed end for driving the implant into the  
9 myometrium or the prostate. This is advantageous as  
10 it means the implant to be left in the body does not  
11 require a pointed portion.

12  
13 According to another aspect of the present  
14 invention, there is provided a tool for inserting a  
15 drug delivery implant into the myometrium or the  
16 prostate, the tool comprising a pointed end for  
17 penetrating the smooth muscle and soft tissue and a  
18 collar for releasably retaining the implant.

19  
20 The implant need not have an integral pointed  
21 portion.

22  
23 Preferably the implant is provided in an insertion  
24 tool the collar of the tool releasably retaining the  
25 implant in the tool while the implant is driven into  
26 the myometrium or the prostate using the tool. The  
27 implant can then be released from the tool when the  
28 implant is suitably located in its intended position  
29 and the tool withdrawn.

30  
31 Preferably the implant further comprises retrieval  
32 means. This is advantageous as it allows the

16

1 implant to be removed after a period of time and  
2 allows control over the length of time a drug is  
3 delivered. Further, it means the delivery device is  
4 not required to be retained in the body forever.

5  
6 Preferably the retrieval means is adapted to allow  
7 the implant to be removed from the myometrium or the  
8 prostate after use.

9  
10 The retrieval means can be any means which allows  
11 the removal of the implant from the myometrium or  
12 the prostate following a determined period of time.  
13 This provides a means for controlling the length of  
14 time over which the drug is delivered.

15  
16 Preferably, the retrieval means comprises a hook at  
17 a proximal end of the implant.

18  
19 Preferably, the body is generally J or U shaped such  
20 that the proximal end of the implant forms a loop or  
21 hook.

22  
23 Alternatively the retrieval means comprises an  
24 elongate flexible member.

25  
26 Preferably the elongate flexible member is a thin  
27 length of cord, twine or fibre.

28  
29 Preferably the elongate flexible member is string.

30  
31 Preferably the elongate flexible member can be left  
32 outside the myometrium and soft tissue surrounding

17

1 the uterus and / or vaginal cavity without causing  
2 irritation to a patient.

3

4 When it is desired to remove the implant, the  
5 flexible member can be manipulated to pull the  
6 implant out of the myometrium.

7

8 Alternatively the retrieval means is capable of  
9 accepting a screwdriver or other means for placing  
10 the implant in the body and/or removing the implant  
11 from the body.

12

13 Preferably the retrieval means can receive an  
14 implant removal device.

15

16 Preferably the medium may be any suitable substance  
17 for carrying a drug to be administered and slowly  
18 releasing it into the myometrium or the prostate,  
19 surrounding soft tissues and blood vessels.

20

21 Preferably the implant comprises a visible or  
22 palpable locator. This is advantageous as it allows  
23 the location of the implant to be determined by  
24 either a visual inspection or by a physical  
25 inspection.

26

27 More preferably the retrieval means is a visible or  
28 palpable locator.

29

30 This is advantageous as the retrieval means is  
31 typically accessible and would allow the location of

18

1 the implant to be checked by visual or physical  
2 inspection.

3

4 Preferably the implant may be left in the myometrium  
5 or the prostate for a prolonged length of time.

6

7 Preferably the implant may be left in the myometrium  
8 or the prostate and the drug delivered over a period  
9 of one month to 5 years.

10

11 The implant may be left in the myometrium or the  
12 prostate and the drug delivered over a period of at  
13 least one hour, 1 day, 1 to 3 months, 1 to 6 months,  
14 1 to 12 months, 1 to 2 years or 1 to 5 years.

15

16 Preferably the medium for carrying the drug is any  
17 suitable pharmacological medium known in the art.

18

19 More preferably the medium for carrying the drug is  
20 a hydrogel, silicone based compound or elastomer.

21

22 Preferably the drug to be delivered cannot be taken  
23 orally.

24

25 Preferably the drug to be delivered promotes a  
26 contraceptive effect.

27

28 Preferably the drug to be delivered is a steroid.

29

30 More preferably the drug to be delivered is a  
31 hormone, for example progestagen.

32

19

1 Preferably the drug to be delivered is  
2 levonorgestrel or etonorgestrel for the provision of  
3 a contraceptive effect.

4  
5 Alternatively, the drug to be delivered is at least  
6 one hormone for hormone replacement therapy (HRT).

7  
8 It can be appreciated that a number of other drugs  
9 may be suitable for delivery by the invention such  
10 as agents for killing cancer cells or treating  
11 cancer, particularly cancer cells of the bladder,  
12 prostate or cervix or other pelvic malignancies. In  
13 these embodiments it is preferable that the drug to  
14 be delivered is cytotoxic.

15  
16 Alternatively the delivery device can deliver one or  
17 more drug means suitable for radiotherapy.

18  
19 The device may also be used to deliver one or more  
20 drugs for the treatment of an over active bladder,  
21 such drugs including anti-cholinergic drugs or  
22 calcium antagonists.

23  
24 A drug delivered by the present invention may also  
25 include a microbicide. A microbicide is any agent  
26 detrimental to, or destructive of, the life of  
27 microbes, viruses or bacterial organisms. Such a  
28 microbicide could be used to destroy organisms  
29 responsible for sexually transmitted diseases such  
30 as gonorrhoea, chlamydia, genital herpes or HIV.

31

20

1 The drug delivery device and method of the present  
2 invention promotes smooth, controlled release of  
3 drugs to a specific site in the body, which allows  
4 absorption of drugs without subjecting drugs to  
5 liver metabolism.

6

7 Embodiments of the present invention will now be  
8 described by way of example only with reference to  
9 the accompanying drawings, in which:

10

11 Figure 1 is an illustration of a first drug  
12 delivery device according to the invention;

13

14 Figure 2 is an illustration of the drug  
15 delivery device of Figure 1 in use;

16

17 Figure 3 is a sectional view of the  
18 illustration in Figure 2 along the line A-A;

19

20 Figure 4 is an illustration of a second drug  
21 delivery device according to the invention;

22

23 Figures 5 and 6 are illustrations of further  
24 embodiments of a drug delivery device according  
25 to the present invention;

26

27 Figure 7 is a sectional view of the  
28 illustration in Figure 2 along line B-B; and

29

30 Figure 8 is an illustration of an embodiment of  
31 an implant of the present invention inserted in  
32 the prostate.



1  
2 Referring to Figure 1, a drug delivery device  
3 comprises an implant 1 having a body 2 and a drug  
4 delivery means 3. The distal end of the body 2 has  
5 a point 4 for penetrating soft tissue and the  
6 proximal end of the body 2 is bent toward the distal  
7 end to provide a hook 5. The bent, curved portion  
8 or hook at the proximal end of the body 2 restricts  
9 the body 2 from becoming buried in soft tissue and  
10 allows retrieval of the implant 1 from soft tissue  
11 and the smooth muscle of the myometrium or the  
12 prostate.  
13  
14 The retrieval means provided by the hook 5 can both  
15 limit movement of the implant into the tissue and  
16 also provide means by which the location of the  
17 implant can be checked by visual or physical means.  
18  
19 The body is metallic and is typically constructed of  
20 surgical steel or titanium.  
21  
22 A portion of the body 2 between the point 4 and hook  
23 5 houses the drug delivery means 3. In this  
24 example, a length of the body 2 between the point 4  
25 and hook 5 has a reduced diameter relative to the  
26 diameter of the body 2 at the distal and proximal  
27 ends. The drug delivery means 3 comprises a  
28 cylinder of material formed around the reduced  
29 diameter portion of the body 2. In this example,  
30 the cylinder or material is a hydrogel carrying the  
31 drug to be delivered by the drug delivery device. In

22

1 another example, the material is a silicone based  
2 material or elastomer.

3  
4 The body 2 has a diameter of 1mm and a length of  
5 40mm. These diameters and lengths are, of course,  
6 for guidance only and other suitable dimensions will  
7 be apparent to those skilled in the art. For  
8 example depending of the amount of drug to be  
9 delivered the length of the body may be 20mm or  
10 60mm.

11  
12 Referring to Figure 2, the female human genital area  
13 comprises a bladder 6, urethra 7, vaginal cavity 8,  
14 cervix 9, uterus 10 and anus 11. In particular, the  
15 cervix 9, at a position between the vaginal cavity 8  
16 and uterus 10, comprises the cervical canal 12  
17 leading from the vaginal cavity 8 into the uterus 10  
18 and surrounding smooth muscle known as the  
19 myometrium 13. The myometrium is defined by the  
20 serosa 20 (an epithelial layer of cells) and the  
21 endometrium 22. A sectional view of the cervix  
22 along line A-A is shown in Figure 3.

23  
24 In use, the implant 1 is passed up the vaginal  
25 cavity 8 to the cervix 9 and inserted into the  
26 myometrium 13. The point 4 of the implant 1  
27 facilitates easy insertion into the smooth muscle of  
28 the myometrium 13. The implant 1 may be manipulated  
29 using any suitable surgical tool during insertion,  
30 such as forceps or the like. No local anaesthetic  
31 is required as the myometrium has very few or no  
32 sensory nerves.

1

2 The drug delivery means is thus implanted into the  
3 myometrium 13. Surrounded by smooth muscle and soft  
4 tissue, the hydrogel located between the point 4 and  
5 the hook 5 slowly releases the drug it contains.

6

7 Depending of the release characteristics of the  
8 hydrogel and the chemical composition of the drug;  
9 release of the drug will typically occur between 1  
10 month to 5 years from implantation.

11

12 During retention of the implant 1 in the myometrium  
13 13, straightforward examination of the vaginal  
14 cavity 8 by a medical practitioner can verify that  
15 the implant 1 is in its intended position in the  
16 myometrium 13. Whilst there is little chance of the  
17 implant 1 becoming displaced, as the hook 5 remains  
18 outside the myometrium 13, any such displacement can  
19 be easily observed.

20

21 The location of the implant in the smooth muscle of  
22 the cervix and part of the body of the smooth muscle  
23 of the uterus of the myometrium allows the implant  
24 to be easily inserted and the location of the  
25 implant to be easily verified by routine  
26 examination.

27

28 Further, the implant is removable from the  
29 myometrium. The location of the implant in the  
30 tissue overcomes the disadvantages associated with  
31 vaginal rings and IUD coils such as discomfort,

24

1 particularly during intercourse, discharge and  
2 religious objections.

3

4 As smooth muscle of the cervix is highly  
5 vascularised and has little somatic innervation,  
6 drug delivery to these tissues show good  
7 pharmacokinetics and insertion of the implant is  
8 relatively painless for the patient.

9

10 Once the implant 1 has reached the end of its useful  
11 life, i.e. the drug has been administered for the  
12 intended length of time, the implant 1 can be  
13 removed by pulling on the hook 5 to withdraw the  
14 implant 1 from the myometrium 13. Again, this is a  
15 straightforward procedure without need for local  
16 anaesthetic.

17

18 Referring to Figure 4, in a second embodiment of the  
19 drug delivery device, an implant 14 comprises a rod  
20 15 bent at a proximal end to form a hook 16. The  
21 hook 16 again allows easy retrieval of the implant  
22 14 from the myometrium 13, along with enabling  
23 straightforward observation of the implant 14 during  
24 use. The rod 15 is made from plastics material  
25 impregnated with a drug to be delivered. The distal  
26 end 17 of the rod 15 is blunt.

27

28 In use, the implant 14 is inserted into the  
29 myometrium 13 in a similar way to the implant 1 of  
30 the first embodiment. However, as the rod 15 of the  
31 implant 14 has a blunt distal end 17, a needle-like  
32 delivery device (not shown) is used to insert the

25

1 implant 14 in the myometrium 13. The delivery  
2 device or tool more specifically comprises a sharp  
3 point for penetrating the smooth muscle of the  
4 myometrium 13 and attachment means for releasably  
5 attaching the implant 14 to the tool. The tool is  
6 driven into the myometrium 13 and the implant 14  
7 released such that the tool can be withdrawn leaving  
8 the implant 14 in place.

9  
10 Wherein the implant itself is the medium by which  
11 the drug to be administered is carried it can be  
12 envisaged that the drug delivery device is a hollow  
13 needle containing the implant and that the implant  
14 is injected into the myometrium 13. The use of  
15 implant comprising the medium of which the drug to  
16 be administered is included, allows insertion of  
17 the implant into the myometrium 13 and delivery of  
18 the drug to be limited to a very short time scale.

19  
20 The drug may be delivered to the myometrium 13 and  
21 be absorbed within a few minutes, hours, days or  
22 weeks depending on the medium. It can be  
23 appreciated that where the implant comprises the  
24 drug delivery medium, removal of the implant is not  
25 required. An absorbable implant therefore does not  
26 require retrieval means.

27  
28 In another example, the implants 1, 14 may be  
29 provided with a string (not shown) attached to the  
30 proximal end of the implant 1, 14. This may be in  
31 addition to the hook 5, 16 or in place of the hook  
32 5, 16. The string allows retrieval of the implant

26.

1 1, 14 by pulling on the string and is useful  
2 particularly where the implant 1, 14 becomes buried  
3 in the soft tissue and smooth muscle of the  
4 myometrium 13.

5  
6 Various improvements and modifications may be made  
7 without departing from the scope of the present  
8 invention. For example, it can be envisaged that  
9 the body of the implant may be formed from  
10 absorbable polymers. This would avoid the need to  
11 remove the implant at a later date. As shown in  
12 figure 5, the implant 25 can be corkscrew shaped.  
13 The implant can comprise retrieval means which  
14 includes a recess 26 capable of accepting a  
15 screwdriver (not shown) or other such means to allow  
16 the implant to be moved into and out of the tissue  
17 of the myometrium or prostate. In an alternative  
18 embodiment the implant can be a cylindrical mesh 30  
19 (as shown in figure 6) which is able to be inserted  
20 into the myometrium or the prostate. An implant of  
21 cylindrical mesh shape would mean there would be an  
22 increased surface area of the implant in contact  
23 with the myometrium than would be present using a  
24 singular rod of similar dimensions. The amount of  
25 surface area of the implant in contact with  
26 surrounding tissue or muscle can influence the drug  
27 delivery characteristics of the implant. The  
28 implant as shown in figure 6 can be pushed into the  
29 myometrium or prostate and removed from the same  
30 using retrieval means 32. A tool (not shown) can be  
31 inserted into the retrieval means to allow removal  
32 of the implant.

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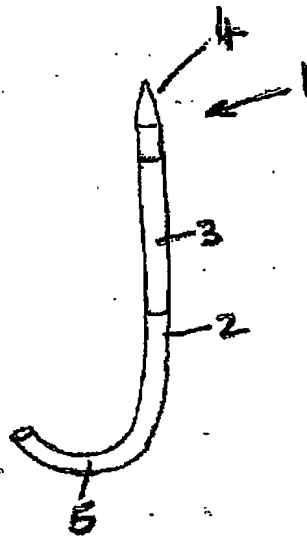


FIGURE 1

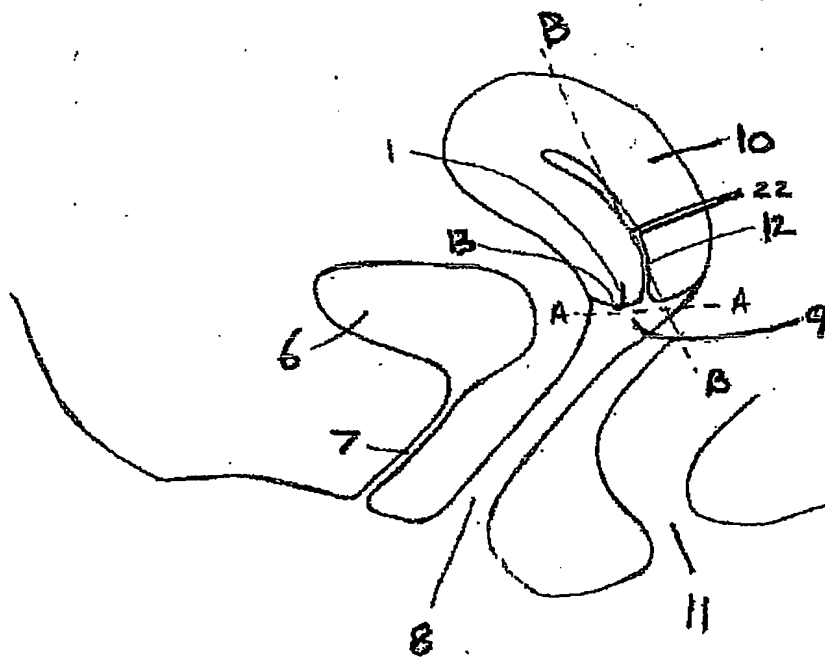


FIGURE 2

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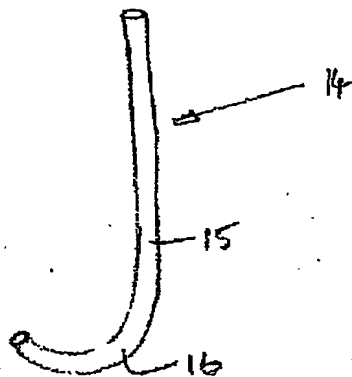


FIGURE 4

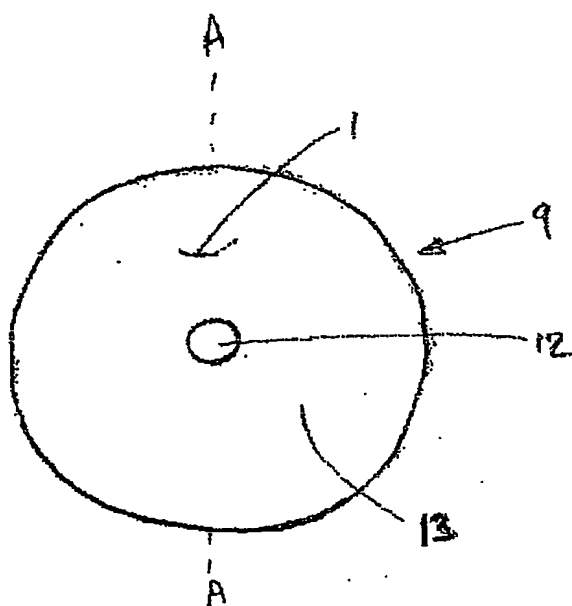


FIGURE 3



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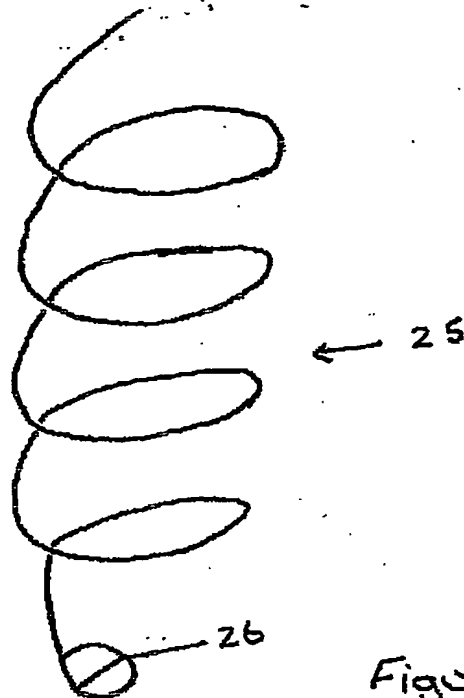


Figure 5.

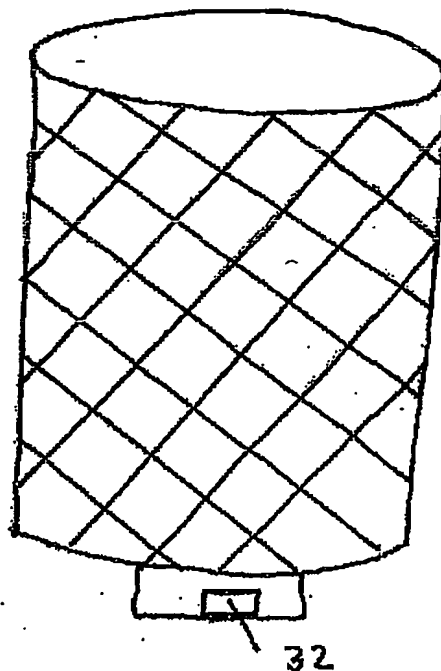


Figure 6

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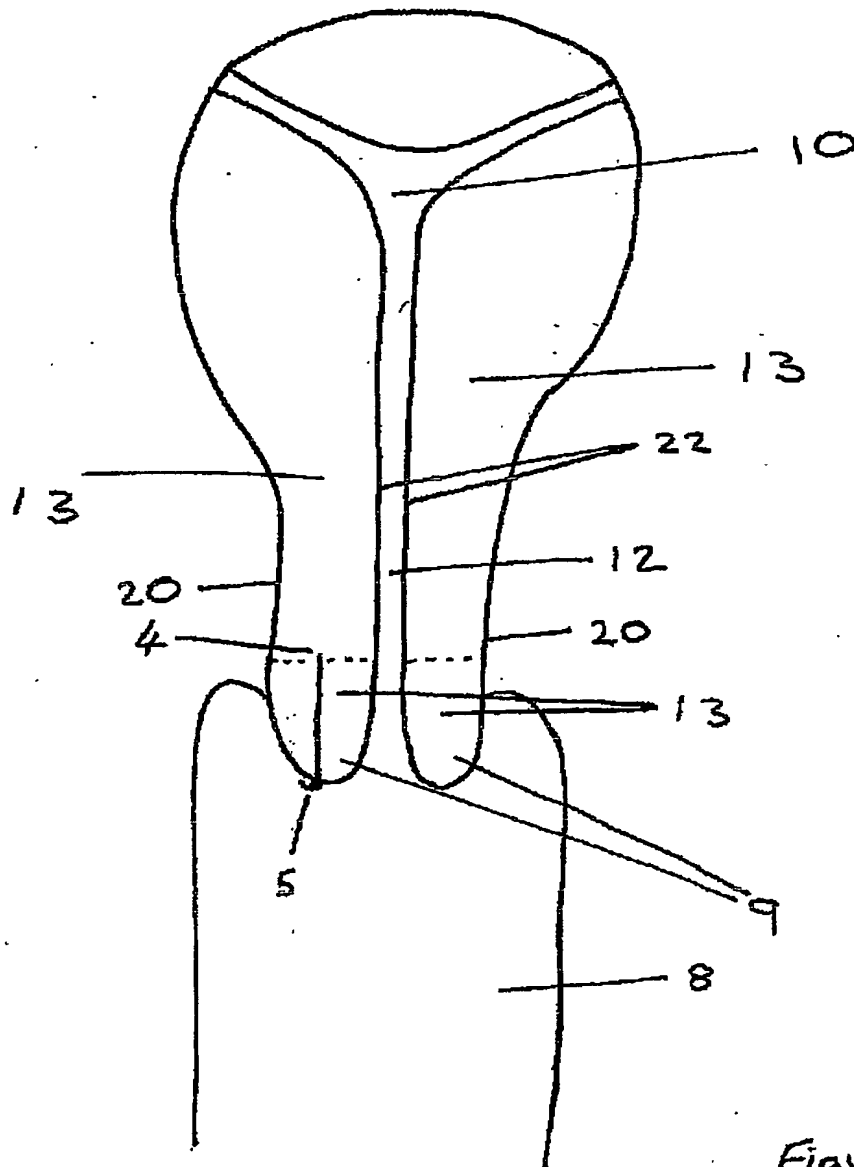


Figure 7

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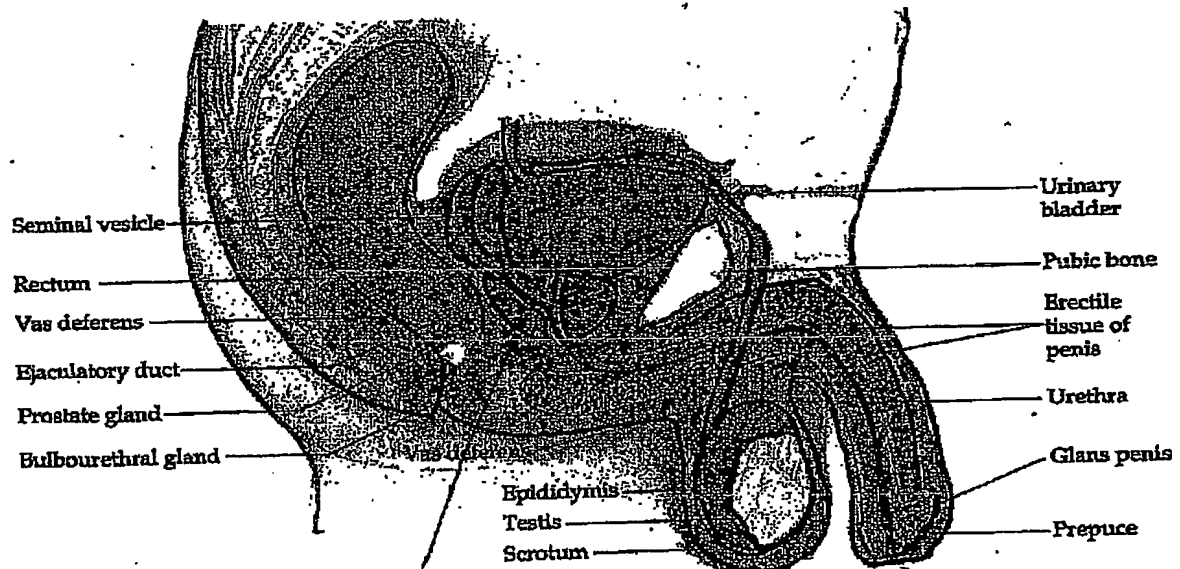


Figure 8